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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,507	02/17/2004	James I. Mullins	016336-001320US	7871

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,507	MULLINS ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Office acknowledges the Preliminary Amendment filed on November 22, 2004. Claims 1-62 are pending and are considered in this Office action.

2. It is noted that claim 62 depends from "The method of claim 28", but claim 28 is directed to "a vector". For restriction purposes, it is assumed to depend on claim 59. Correction is required.

3. Claims 7, 10, 11, 48 and 55 should be amended to refer an mrca, Lscot or Mmcot sequence to specific SEQ ID number rather than to sequences from Figures.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 15-30, drawn to an isolated ancestral viral gene sequence, an expression vector and a cultured prokaryotic or eukaryotic cell, classified in class 536, subclass 23.72; class 435, subclass 320.1; and class 435, subclass 240.2.

II. Claims 9-14, drawn to an isolated ancestor protein, classified in class 530, subclass 350.

III Claims 31-34, drawn to a composition for inducing an immune response in a mammal, classified in class 435, subclass 236.

IV. Claims 35-39, drawn to an isolated antibody against an ancestral protein, classified in class 435, subclass 810.

V. Claims 57 and 58, drawn to an isolated antibody against a COT protein, classified in class 435, subclass 810.

VI. Claims 45-51 and 15-30, drawn to a COT viral gene sequence, an expression vector and a cultured prokaryotic or eukaryotic cell, classified in class 536, subclass 23.72; class 435, subclass 320.1; and class 435, subclass 240.2.

VII. Claims 52-56, drawn to a COT protein, classified in class 530, subclass 350.

VIII. Claims 40-44, drawn to a method of preparing an ancestral viral amino acid sequence, classified in class 702, subclass 19.

IX. Claims 59-62, drawn to a method of preparing a COT viral amino acid sequence, classified in class 702, subclass 19.

5. Groups I-VII are different products. Groups I-VII are directed to patentably distinct virus sequences, proteins, and antibodies, wherein each has a different structure and biological property, and wherein each is capable of separate manufacture and use.

6. Groups VIII and IX are different methods. A method of preparing an ancestral viral amino acid sequence of Group VII differs from a method of preparing a COT viral amino acid sequence of Group VIII with respect to method steps and endpoints. Therefore, each method is patentably distinct.

7. Groups II and VIII are related as process of making and product made. Groups II is directed to an isolated ancestor protein, while Group VIII is directed to a method of making an ancestral viral amino acid sequence. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different

process (MPEP § 806.05(f)). In the instant case, a COT protein could be isolated from a sample

8. Groups V and IX are related as process of making and product made. Groups V is directed to a COT protein, while Group IX is directed to a method of making a COT amino acid sequence. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, an ancestral amino acid sequence could be isolated from a sample.

9. Groups III and VIII/IX are related as process of making and product made. Groups III is directed to a vaccine composition of a viral ancestor protein or COT protein, while Group VIII/IX are directed to a method of making an viral ancestral or COT amino acid sequence. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a vaccine composition could be made by an isolated viral protein from a sample.

10. Groups I/IV/V/VI and VIII/IX are unrelated. The products of an ancestral or COT gene sequence and an antibody of Groups I/IV/V/VI are separate and distinct from the methods of Group VIII/IX, wherein the products of viral gene sequence and an antibody is neither be made by nor used in the methods.

11. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field

of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Since it is an undue burden for the Office to search more than one invention, a restriction for examination purposes as indicated is proper.

Species Election

12. This application contains claims directed to patentably distinct species of the claimed invention. If any of Group I, II, III, V OR VI is elected, Applicant must further elect a single sequence by a SEQ ID NO.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

17. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

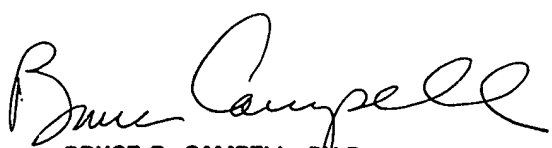
18. Applicant is reminded the upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance the 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Bo Peng, Ph.D.



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